

# EXHIBIT A

**Report of Matthew C. Lee, M.D., R.Ph., M.S.  
Re: Brittany Henley**

I submit this written statement based on my review of records and information available to me pertaining to epidural steroid injections administered to Brittany Henley and her subsequent treatment for fungal meningitis. The information was obtained from review of Ms. Henley's records from Dallas Back Pain Management and New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center and the United States Food and Drug Administration.

Brittany Henley received steroid injections into the epidural space of lumbar spine and multiple facet joints of the lumbar spine at Dallas Back Pain Management on September 27, 2012 by Abbaselom Ghermay, MD. The injections contained methylprednisolone acetate (80 mg/ml (DepoMedrol®), according to Ms. Henley's records.

The steroid injected into Ms. Henley was preservative free methylprednisolone acetate ("MPA") procured from an out of state compounding pharmacy known as New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center ("NECC"). NECC records show that this medication was part of a shipment of one-hundred, 80 mg/ml, 5 ml (multi-dose) vials from NECC to Dallas Back Pain Management with shipping date August 24, 2012.

**Qualifications**

I am a physician licensed to practice medicine in the State of Virginia. I am licensed to practice pharmacy in the States of Virginia, North Carolina and Kentucky. I have been in practice in Virginia as a primary care physician since 2006. I have been practicing pharmacy since 1995. I am a practicing physician, pharmacist, pharmacologist and toxicologist.

I am familiar with the applicable standard of care pertaining to and concerning the procurement and administration of epidural steroid injections to patients such as Brittany Henley. In my opinion, the standards of care are national standards of care and are the same in Dallas, TX as compared to Richmond, Virginia.

Accordingly, I believe that I am competent to express opinions regarding the fields of Medicine, Pharmacy, Pharmacology and Toxicology as they apply in this case.

**Parties**

It is my understanding that Dallas Back Pain Management is located in Dallas TX. Abbaselom Ghermay, MD is an owner/manager of Dallas Back Pain Management.

It is further my understanding that according to information compiled by the United States Food and Drug Administration, Dallas Back Pain Management purchased 100 vials of preservative free methylprednisolone acetate ("MPA") from an out of state compounding pharmacy known as New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center ("NECC") on August 24, 2012.

### Information Reviewed

My statements are based on information taken from the patient's medical records from Dallas Back Pain Management and documentation from the FDA and NECC. I have also reviewed certain information pertaining to NECC provided to me by counsel.

Based upon that information, I understand the facts regarding this individual patient to be as follows: Ms. Brittany Henley was diagnosed with and treated for fungal meningitis resulting from the steroid injection she received at Dallas Back Pain Management on September 27<sup>th</sup>, 2012. Brittany Henley received steroid injections of methylprednisolone acetate 80 mg/ml into the epidural space of lumbar spine and multiple facet joints of the lumbar spine at Dallas Back Pain Management on September 27, 2012 by Abbeselom Ghermay, MD. The injections contained methylprednisolone acetate (80 mg/ml (DepoMedrol<sup>®</sup>), according to Ms. Henley's records. An injection of 80 mg, 1 ml, was administered into the epidural space and six injections containing 8 mg (0.1 ml) of methylprednisolone acetate were injected bilaterally to the facet joints at the levels of L3/L4, L4/L5 and L5/S1, one injection at each level on each side.

On October 7<sup>th</sup>, 2012 Ms. Henley reported a three day history of worsening headaches and was told to go the emergency room. A cerebrospinal fluid (CSF) sample was obtained via lumbar puncture, which was culture positive for mold. Ms. Henley was started on the antifungal medications voriconazole and amphotericin. Organisms isolated from her cerebrospinal fluid culture were, consistent with the contaminants identified in the preservative free methylprednisolone acetate manufactured/compounded by NECC during this time period.

### NECC History

Based on information previously provided to me, I am aware of the following concerning NECC.

NECC began operations in June 1998. The first enforcement action against NECC began in April 1999, just 10 months after it obtained its license. The Massachusetts Board of Registration in Pharmacy (the "MA Board") filed a complaint stating that NECC was including blank prescriptions in its solicitations to doctors, in violation of state law.

In 2002, a physician reported to the FDA that at least five patients had become ill following epidural injections that contained NECC medications.

In July 2002, William Koch contracted bacterial meningitis after being injected with contaminated MPA compounded by NECC. Mr. Koch eventually died from complications related to the infection. In 2004, Mr. Koch's family sued the NECC and the medical providers who performed the injection. The case was later settled.

In August 2002, additional adverse events were reported to the FDA concerning patients who had contracted meningitis. The suspected source of the infections were epidural injections that contained methylprednisolone acetate compounded by NECC. The FDA investigated NECC following the adverse events and found that five of 16 vials were contaminated with bacteria. The investigators concluded "sample results revealed that the firm has sterility and potency issues with injectable steroid suspensions (betamethasone repository USP and methylprednisolone acetate USP)."

In December 2006, the FDA issued a Warning Letter to NECC. The letter details numerous problems at NECC including the sale of compounded drugs without patient-specific prescriptions, compounding copies of commercially available drugs, selling misbranded compounded drugs, and problems with storage and sterility. That warning letter has been available to the public on the FDA's website for years. The FDA posted that letter under the heading "Significant Compliance Actions."

In 2011, the Colorado Board of Pharmacy issued a Cease and Desist letter to NECC as a result of distribution of non-patient specific compounded drugs to hospitals in Denver.

In September 2012, health officials identified an outbreak of fungal meningitis. Investigators traced the outbreak to medication compounded by NECC. To date, more than 700 people have been sickened by medications compounded by NECC and more than 60 people have died.

#### Dangers of Compounded Drugs

The risks of pharmacy compounding have been the subject of considerable public discussion in the pharmacy community and the medical community. Compounding pharmacies are not subject to the same FDA regulations as drug manufacturers and compounded drugs are not FDA approved.

The American Society of Health System Pharmacists ("ASHP") has also played an active role in warning the pharmacy and medical communities of the risks of using compounded drugs. In 2010 the ASHP published the "ASHP Guidelines on Outsourcing Sterile Compounding Services." They also developed a "Contractor Assessment Tool" for healthcare organizations to use in conjunction with their guidelines. That document was developed to be used by health systems when deciding whether and from where they should purchase compounded medications.

The guidelines state that health systems should perform certain due diligence before purchasing drugs from compounders. For example, before buying compounded drugs, the purchaser should: (1) have an employee or agent visit the compounding pharmacy; (2) determine whether the compounding pharmacy has had product liability lawsuits filed against it; (3) determine whether the compounding pharmacy has ever recalled any of its compounded preparations; and (4) review regulatory surveys conducted of the compounding pharmacy's site, including copies of significant regulatory actions.

#### Standards of Care and Violations of Standards of Care

It is my opinion that the recognized standard of acceptable professional practice of medicine, specifically as it relates to the acquisition, storage and administration of sterile medications by injection in all medical practices and specialties in Dallas TX and similar communities as it existed during the 12-month period preceding and including September, 2012, would require a clinic such as Dallas Back Pain Management and its medical director and managers, to exercise due care in selecting and procuring steroids for injection into patients in order to assure that the source of the medications is reliable and safe.

One of the first red flags that should have raised attention that corners were being cut, was that NECC was willing to circumvent state laws and/or regulations governing the

requirements for the procurement of such medications. This happens to be one of the requirements that differentiates compounding medications vs. manufacturing medications.

It is further my opinion that the recognized standard of acceptable professional practice in Medicine and Pharmacy in Dallas, TX and similar communities during 2012 would require a clinic such as Dallas Back Pain Management and its medical directors and managers, to undertake a sufficient and appropriate investigation of the source of epidural steroids and, in the event the medical director decided to procure epidural steroids from a compounding pharmacy, to determine that the pharmacy is a safe and reputable supplier of injectable steroids. Such due diligence should, at a minimum, include a site visit and/or background investigation consistent with the guidelines published by the American Society of Health System Pharmacists.

It is further my opinion that the entities and/or persons who decided to purchase preservative-free methylprednisolone acetate ("MPA") from NECC for administration to patients at Dallas Back Pain Management fell below the applicable standard of care as that standard of care existed in Dallas, TX and similar communities during 2012, in that they did not exercise appropriate due diligence by conducting a site visit and/or appropriate investigation of NECC. At a minimum, a cursory inquiry into NECC more likely than not would have revealed the alarming history as outlined above, which would have caused a reasonable pain clinic exercising ordinary care to avoid NECC as a source of compounded pharmaceuticals due to, among other things, an increased risk of contaminated medications. Here, the vial of medication used on Brittany Henley was a preservative-free steroid sent by NECC to Dallas Back Pain Management on August 24, 2012 and not used until September 27, 2012. To be in keeping with applicable standards of care for a pain clinic, Dr. Ghermay and Dallas Back Pain Management should have assured that compounded preservative-free medications it used were not only from a reputable source but were also patient-specific and used promptly rather than purchased in bulk and used after month(s)-long storage.

Because of the violations of the applicable standards of care outlined above, Dr. Ghermay and Dallas Back Pain Management purchased contaminated medications from a high-risk source in bulk and stored the vial in question for over one month before injecting the medication into Brittany Henley. The injection deposited dangerous pathogens directly into Henley's epidural space causing a life-threatening fungal meningitis infection.

Based upon the information available to me from the medical records and other sources concerning the care and treatment of Brittany Henley there is a good faith basis to maintain an action against Abbeselom Ghermay, MD, Dallas Back Pain Management, and any other persons or entities responsible for the procurement of the subject steroids from NECC including its managers and owners. It is my opinion that to the extent the medical director and manager of Dallas Back Pain Management made the decision to purchase the subject steroids from NECC without the involvement of a pharmacist and a reasonable investigation into NECC, there is a good faith basis to maintain an action against the medical director and manager of Dallas Back Pain Management.

  
Matthew C. Lee, MD, RPh, MS  
PHYSICIAN, PHARMACEUTIST, PHARMACEUTICAL CONSULTANT & TOXICOLOGIST

April 8, 2014

Date

# EXHIBIT B

4/7/2014

## CURRICULUM VITAE



### **MATTHEW C. LEE, MD, RPH, MS**

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## I. EMPLOYMENT



**Physician. eLEETe Physicians, LLC, Primary Care Practice.** Primary care physician (PCP). Primary Care medical practice, diagnose and treat general medical conditions of adult patients 18 years old and over.



**Pharmacist. Parallon Solutions.** Provide patient care activities to ensure safe and effective drug therapy. Accurately enter orders in the computer and timely manner. Screen for drug interactions, allergies, or duplications, appropriate diagnosis, renal and liver function prior to order entry. Investigate and report adverse drug events and medication incidents. Review and interpret all physician orders received using patient profiles. Monitor for incompatibilities, concentration and rate of intravenous drugs. Assess orders for age specific appropriateness from neonatal through geriatric. Dissemination of drug information.



**Medical Examiner for the Central District of the Office of the Chief Medical Examiner for the jurisdictions of Chesterfield, Hanover and Henrico counties and Richmond city.** Appointed by the Chief Medical Examiner for a three year term, until September 30, 2014.



**Veterans Evaluation Services Provider.** Perform Forensic Legal Examinations of U.S. Military Veterans evaluating and assessing the extent of functional limitations or impairment related to a claimed condition.



**Physician. Apple Mobile Medical.** Occupational Health Physician at Teva Pharmaceuticals. Perform annual Employee Health Surveillance and pulmonary assessments on employees required to wear respirators. One to two weeks per year.



## II. WORK HISTORY:



Physician. United States Department of Defense, Military Entrance Processing Station (MEPS), Fort Lee Virginia. Physician, perform physicals on new military recruits to determine medical qualification as required for entrance into any branch of the U.S. Military as defined by the protocols established the U.S. Department of Defense.



Physician. Apple Mobile Medical Occupational Health. Perform Personal Health Assessments on Pre- and Post- deployment soldiers in the United States National Guard.



Physician. Locum Tenens in Occupational Health and Family Practice for Jackson and Coker.

Zelda West Johnson, MD and Associates Family Practice- Physician in Family Practice.

Pharmacist, Walnut Hill Pharmacy, Petersburg, VA

Pharmacist; Poplar Springs Hospital; Petersburg, VA.

Pharmacist for Wal-Mart pharmacy, as needed throughout Virginia

Pharmacy Manager; Wal-Mart Pharmacy; Tarboro, NC.

Lab Technician; Medical College of Virginia, Department of Pharmacology; Richmond, VA.

Pharmacist; Prince George Pharmacy; Prince George, VA.

## III. EDUCATION AND TRAINING



Undergraduate - Barton College (previously Atlantic Christian College). September 1988 – May 1990.



Undergraduate - Virginia Commonwealth University, Bachelor's of Science in Chemistry. August 1992.



Professional - Medical College of Virginia, School of Pharmacy, Bachelor's of Science in Pharmacy (B.Pharm). May 1995.





Graduate - Virginia Commonwealth University Department of Pharmacology/Toxicology. **Master's of Science in Pharmacology and Toxicology.** September 1997 – August 1999.  
**Thesis: The Role of several kinases in mice tolerant to delta-9 Tetrahydrocannabinol.**



Doctoral - Virginia Commonwealth University School of Medicine, **Doctor of Medicine (M.D.).** May 2004.



Post-Doctoral - Internship in Internal Medicine, Virginia Commonwealth University Medical Center. July 2004 – June 2005.

#### IV. CERTIFICATIONS AND LICENSURE



Musculoskeletal Exam and Treatment Techniques, American College of Occupational and Environmental Medicine.



Medical Review Officer, Certified by American College of Occupational and Environmental Medicine.



Commonwealth of Virginia, license to practice medicine and surgery, since 2005



Commonwealth of Virginia, license to practice pharmacy, since 1995



State of North Carolina license to practice pharmacy, since 1999



Commonwealth of Kentucky license to practice pharmacy, since 2013

#### V. APPOINTMENTS



**Medical Examiner** for the Central District of the Office of the Chief Medical Examiner for the jurisdictions of Chesterfield, Hanover and Henrico counties and Richmond city. Appointed by the Chief Medical Examiner for a three year term, until September 30, 2014.



**National Association of Boards of Pharmacy Licensure Exam (NABPLEX) question writer.**



**National Academy of Sciences, Science & Entertainment Exchange Consultant.**



**CBS Criminal Minds.**



**Journal of Clinical Pharmacology Peer Review Board.**



**DynaMed Editorial Team Reviewer.**  
<http://www.ebscohost.com/dynamed>.

## VI. PUBLICATIONS AND RESEARCH PRESENTATIONS



**Medical Marijuana in the Workplace.** A White Paper Prepared by the ACOEM Pharma and MRO Sections. ACOEM Position Paper on Medical Marijuana. Reviewer/editor.



ACOEM Medical Review Officer Review committee for the proposed rule to establish FMCSA Clearinghouse for drug and alcohol test results.



**Two Cases of Alleged Dilaudid<sup>®</sup> Overdose: Sometimes it is, sometimes it is not.** Matthew C. Lee, MD, RPh, MS. June 2013. [www.HGExperts.com](http://www.HGExperts.com), [www.JurisPro.com](http://www.JurisPro.com), [www.ExpertPages.com](http://www.ExpertPages.com).



**DynaMed Editorial Team. Lee, M (Reviewer). Neuroleptic Malignant Syndrome.** Last updated 2012 05 01. Available from DynaMed: <http://www.ebscohost.com/dynamed>.



**DynaMed Editorial Team. Lee, M (Reviewer). Paralytic Shellfish Poisoning.** Last updated 2012 06 21. Available from DynaMed: <http://www.ebscohost.com/dynamed>.



**DynaMed Editorial Team. Lee, M (Reviewer). Anti-Cholinergic Poisoning.** Last updated 2012 11 27. Available from DynaMed:

<http://www.ebscohost.com/dynamed>.

Assessment of Marijuana Intoxication. Matthew C. Lee, MD, RPh, MS. October 4<sup>th</sup>, 2010. [www.HGExperts.com](http://www.HGExperts.com), and [www.ExpertPages.com](http://www.ExpertPages.com).  
Quantum Free Will. Matthew Lee. *New Scientist*. September 1<sup>st</sup>-7<sup>th</sup>, 2007; 195(2619):25.  
<http://www.newscientist.com/article/mg19526195.100-quantum-free-will.html>



The Role of Several Kinases in Mice Tolerant to Delta-9 Tetrahydrocannabinol. M. Lee, D. Stevens, S. Welch. *Journal of Pharmacology and Experimental Therapeutics*. 2003 May; 305(2):593-9.  
<http://jpet.aspetjournals.org/content/305/2/593.full.pdf+html>



The Effects of Blocking Several Kinases in Mice Tolerant to Δ9-THC. Matthew C. Lee, David L. Stevens and Sandra P. Welch. Virginia Academy of Sciences May 1999.



Reversing Δ9-THC Antinociceptive Tolerance by Inhibiting the Phosphorylation of the CBI Receptor. Matthew C. Lee, David L. Stevens and Sandra P. Welch. FASEB, 1999.



The Role of Several Kinases in Mice Tolerant to Δ9-THC. Matthew C. Lee, David L. Stevens and Sandra P. Welch. International Cannabinoid Research Society, 1999.

## VII. HONORS AND AWARDS



Distinguished Service Award. Virginia Commonwealth University.



University Leadership Award. Virginia Commonwealth University.



Local Association President's Award. Virginia Pharmacist's Association.



Professionalism Award. American Pharmaceutical Association/McNeil Consumer Products.



**Allen and Hanbury's Pride in Pharmacy Scholarship Award.**

**ALLEN & HANBURY'S**

The specialized respiratory division of  
GlaxoSmithKline

**VIII. VOLUNTEER ACTIVITIES**

Physician Volunteer, Fan Free Clinic, Richmond, VA.

Foundations of Clinical Medicine Assistant Instructor.

Professionalism Workshop Group Leader.

Virginia Pharmacist's Association Board of Directors.

Speaker's Bureau for the Pitt County (North Carolina) AIDS Service Organization  
(PICASO).

**IX. PROFESSIONAL MEMBERSHIP**



**American College of Clinical Pharmacology**



**American College of and Occupational and Environmental Medicine**



**American College of Forensic Examiners Institute**



**American Medical Association**



**American Pharmacists Association**



**Medical Society of Virginia**



**American Society of Pharmacy Law**

**Richmond Academy of Medicine**